June 18, 2026

Vincent Healthcare Products Limited
% Paul Dryden
President
ProMedic, LLC
131 Bay Pt. Dr. NE
St. Petersburg, Florida 33704

Re: K252066
Trade/Device Name: inspired™ Heated Breathing Circuit (510-008); inspired™ Heated Breathing Circuit (510-009); inspired™ Auto-feed Humidification Chamber (VHC10); inspired™ Auto-feed Humidification Chamber (VHC20)
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing system heater
Regulatory Class: Class II
Product Code: BZE, BTT
Dated: July 1, 2025
Received: July 1, 2025

Dear Paul Dryden:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn

(https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

John S. Bender -S

*for* Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K252066

Device Name
inspired Heated Breathing Circuit - 510-008 - Adult and 510-009 - Infant

inspired Auto-feed Humidification Chamber - VHC 10 and VHC 20

Indications for Use *(Describe)*
The inspired™ Heated Breathing Circuit acts as a heated conduit to deliver warmed and humidified medical gases to adult and infant patients experiencing respiratory conditions requiring mechanical ventilation, positive pressure breathing assistance or other respiratory support. This is a non-sterile single use product. To be used by trained clinical personnel in a hospital environment only. Compatible with the inspired™ VHB20 Heated Humidifier.

This inspired™ Auto-feed Humidification Chamber acts as a reservoir for water for inhalation. In conjunction with a humidifier, this water is heated to warm and humidify medical gases delivered to patients experiencing respiratory conditions requiring mechanical ventilation, positive pressure breathing assistance or other respiratory support. This is a non-sterile single use product. To be used by trained clinical personnel in a hospital environment only. Compatible with the inspired™ VHB20 Heated Humidifier.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**Date Prepared:** 18-Jun-2026

**Submitter:**
Vincent Healthcare Products Limited
Flat/RM B2, 7/F., Hang Fung Industrial Building,
Phase 2, 2G Hok
Yuen Street, Hung Hom, Kowloon, Hong Kong
Tel. +852 2365 5688

**Submitter Contact:** Thomas Chan, RA Supervisor

**Submission Correspondent:**
Paul Dryden
ProMedic, LLC

**Subject Device 1**

| | |
|---|---|
| Proprietary or Trade Name: | inspired™ 510-008 Adult Heated Breathing Circuit |
| Common/Usual Name: | heater, breathing system w/wo controller (not humidifier or nebulizer) |
| Classification Name: | Breathing system heater<br>21 CFR 868.5270 |
| Product Code: | BZE |

**Predicate 1 Device:**
K122432 – Fisher & Paykel RT380 and RT 385 Adult Evaqua 2 Dual Heated Breathing Circuit

**Subject Device 2**

| | |
|---|---|
| Proprietary or Trade Name: | inspired™ 510-009 Infant Heated Breathing Circuit |
| Common/Usual Name: | heater, breathing system w/wo controller (not humidifier or nebulizer) |
| Classification Name: | Breathing system heater<br>21 CFR 868.5270 |
| Product Code: | BZE |

**Predicate 2 Device:**
K103767 – Fisher & Paykel RT265 Dual Heated Infant Breathing Circuit

**Subject Device 3**

| | |
|---|---|
| Proprietary or Trade Name: | inspired™ VHC10 Auto-feed Humidification Chamber |

| | |
|---|---|
| | inspired™ VHC20 Auto-feed Humidification Chamber |
| Common/Usual Name: | humidifier, respiratory gas, (direct patient interface) |
| Classification Name: | Respiratory gas humidifier<br>21 CFR 868.5450 |
| Product Code: | BTT |

**Predicate 3 Device**
K934140 – MR290 Humidification Chamber Single Use

**Device Description**
The inspired™ Heated Breathing Circuit acts as a heated conduit to deliver warmed and humidified medical gases to adult and infant patients experiencing respiratory conditions requiring mechanical ventilation, positive pressure breathing assistance or other respiratory support.

The inspired™ Heated Breathing Circuit consists of two tube(s) with heater wires, one spare tube without heating wires and other joints. The heater wire placed internally to the tubes is heated by the humidifier's controller power supply and to minimize the loss of humidity.

The inspired™ Heated Breathing Circuit is an active device connected to a AC22V or DC24V power supply from the heated humidifier.

The inspired™ Auto-feed Humidification Chamber is a water reservoir placed between the heated humidifier and the heated wire circuit. It transfers heat from the humidifier to warm and humidify medical gases.

These are non-sterile, single use products.

**Indications for Use**

The inspired™ Heated Breathing Circuit acts as a heated conduit to deliver warmed and humidified medical gases to adult and infant patients experiencing respiratory conditions requiring mechanical ventilation, positive pressure breathing assistance or other respiratory support. This is a non-sterile single use product. To be used by trained clinical personnel in a hospital environment only. Compatible with the inspired™ VHB20 Heated Humidifier.

This inspired™ Auto-feed Humidification Chamber acts as a reservoir for water for inhalation. In conjunction with a humidifier, this water is heated to warm and humidify medical gases delivered to adult and infant patients experiencing respiratory conditions requiring mechanical ventilation, positive pressure breathing assistance or other respiratory support. This is a non-sterile single use product. To be used by trained clinical personnel in a hospital environment only. Compatible with the inspired™ VHB20 Heated Humidifier.

## Comparison of Technological Characteristics and Performance with the Predicates

### Table 1 - Adult Heated Breathing Circuit Comparison of Subject vs. Predicate

| | Predicate Device<br>Fisher & Paykel<br>RT380 Adult Dual Heated Breathing Circuit | Subject Device<br>Vincent Medical<br>inspired™ 510-008 Adult Heated Breathing Circuit | Comparison |
|---|---|---|---|
| **K#** | K122432 | K252066 | |
| **Product Code** | BZE | BZE | |
| **CFR** | 21 CFR 868.5270 | 21 CFR 868.5270 | |
| **Patient Population** | Adult | Adult | |
| **Intended use environment** | Hospital | Hospital | |
| **Intended users** | Respiratory Therapists | To be used by trained medical personnel | Similar |
| **Sterility** | Non-sterile | Non-sterile | Similar |
| **Indications for Use** | The RT380 and RT385 'Adult Evaqua 2' dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of adult patients, and to maintain the temperature of humidified inspired gas. | The inspired™ Heated Breathing Circuit acts as a heated conduit to deliver warmed and humidified medical gases to adult patients experiencing respiratory conditions requiring mechanical ventilation, positive pressure breathing assistance or other respiratory support. This is a non-sterile single use product. To be used by trained clinical personnel in a hospital environment only. Compatible with the inspired™ VHB20 Heated Humidifier. | Similar |
| **Principle of Operation** | The RT380/RT385 breathing circuits form part of a respiratory humidification system in which the inspiratory limb delivers humidified gas to the patient and the expiratory limb carries the expired gas away from the patient. Heater wires in the inspiratory and expiratory limbs minimize the formation of condensate. | The Heated breathing circuit acts as a conduit to transfer warmed and humidified medical gas from the humidifier to the patients. The heater wires incorporated in the breathing circuit are electrically powered by the humidifier to maintain the temperature of the medical gas and minimize the formation of condensate. | Similar |
| **Wire resistance (ohm)** | RT380: Inspiratory – 17.3 Ω; Expiratory – 22.7 Ω | 510-008: Inspiratory - (16±2) Ω; Expiratory - (12±1) Ω | Similar Wire resistance is matched to the compatible heater base |
| **Tube length (m)** | RT380: Inspiratory – 1.6m; Expiratory – 1.6m | 510-008: Inspiratory – 1.7m, Expiratory – 1.7m | Similar |
| **Spare tube** | Provided | Provided 0.5 m long | Similar |

| | Predicate Device<br>Fisher & Paykel<br>RT380 Adult Dual Heated Breathing Circuit | Subject Device<br>Vincent Medical<br>inspired™ 510-008 Adult Heated Breathing Circuit | Comparison |
|---|---|---|---|
| **Tube structure and minimum internal diameter** | Inspiratory – Corrugated 20mm<br>Expiratory – Corrugated 20mm | Inspiratory – Corrugated 20mm;<br>Expiratory – Corrugated 20mm | Similar |
| **Therapeutic use** | Non-invasive<br>Invasive | Non-invasive<br>Invasive | Similar |
| **Flow rates** | Non-invasive: 5-120 L/min<br>Invasive: 5-60 L/min | Non-invasive – 5 - 120 lpm<br>Invasive – 5 – 60 lpm | Similar |
| **Maximum operating pressure** | 8 kPa (80 $cmH_2O$) | 80 $cmH_2O$ | Similar |
| **Compatibility with the environment and other devices** | To be used with F & P MR290 Humidification Chamber. Compatible with F & P MR850 Respiratory Gas Humidifier. | To be used with VHC20 Auto-feed Humidification Chamber. Compatible with inspired™ VHB20 Heated Humidifier | Similar<br>VHB20 has been cleared under 510(k) K222351 and is equivalent to MR850.VHB20 has demonstrated compatibility with RT380 in K222351. |
| **Performance Standards (Standards met)** | ISO 5367<br>ISO 5356<br>ISO 8185<br>IEC 60601-1<br>IEC 60601-1-2 | ISO 5367<br>ISO 5356-1<br>ISO 80601-2-74<br>IEC 60601-1<br>IEC 60601-1-2 | Similar<br>ISO 8185 has been replaced by ISO 80601-2-74. |
| **Electrical Safety and EMC** | IEC 60601-1 compliant<br>IEC 60601-1-2 compliant | IEC 60601-1 compliant<br>IEC 60601-1-2 compliant | Similar |
| **Power / Energy Source** | Wire resistance provides heat to the air passing through the tubing to reduce the water condensation in the breathing system. | Wire resistance provides heat to the air passing through the tubing to reduce the water condensation in the breathing system. | Similar<br>ISO 8185 has been replaced by ISO 80601-2-74. |
| **Biocompatibility** | ISO 10993 compliant | ISO 10993 compliant<br>ISO 18562 compliant | Similar |

**Table 2 - Infant Heated Breathing Circuit Comparison of Subject vs. Predicate**

| | Predicate<br>Fisher & Paykel<br>RT265 Dual Heated Infant Breathing Circuit | Subject device<br>Vincent Medical<br>inspired™ 510-009 Infant Heated Breathing Circuit | Comparison |
|---|---|---|---|
| **K#** | **K103767** | **K252066** | |
| **Product Code** | **BZE** | **BZE** | |
| **CFR** | **21 CFR 868.5270** | **21 CFR 868.5270** | |
| **Target Population** | Infant | Infant | Similar |
| **Intended use environment** | Hospital | Hospital | Similar |
| **Intended users** | Respiratory Therapists | To be used by trained medical personnel | Similar |
| **Sterility** | Non-sterile | Non-sterile | Similar |
| **Indications for Use** | The dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of infant patients, and to maintain the temperature of humidified inspired gas. The RT265 is used for flow rates greater than 4 L/min, and the RT266 is for flow rates between 0.3 and 4 L/min. | The inspired™ Heated Breathing Circuit acts as a heated conduit to deliver warmed and humidified medical gases to infant patients experiencing respiratory conditions requiring mechanical ventilation, positive pressure breathing assistance or other respiratory support. This is a non-sterile single use product. To be used by trained clinical personnel in a hospital environment only. Compatible with the inspired™ VHB20 Heated Humidifier. | Similar |
| **Principle of operation** | Infant breathing circuits form part of the respiratory humidification system in which the inspiratory limb delivers humidified gas to the patient and the expiratory limb carries the expired gas away from the patient. Heater wires in the inspiratory and expiratory limb minimize the formation of condensate. | The Heated breathing circuit acts as a conduit to transfer warmed and humidified medical gas from the humidifier to the patients. The heater wires incorporated in the breathing circuit are electrically powered by the humidifier to maintain the temperature of the medical gas and minimize the formation of condensate. | Similar |
| **Tube length (m)** | Inspiratory – 1.6m; Expiratory – 1.6m | Inspiratory – 1.6m; Expiratory – 1.6m | Similar |
| **Spare tube** | Provided | Provided – 0.64 m long | Similar |
| **Wire resistance (ohm)** | Inspiratory – 21.9Ω<br>Expiratory – 22.5Ω | Inspiratory – (22±0.8) Ω<br>Expiratory– (22±0.8) Ω | Similar |
| **Tube structure and minimum internal diameter** | Inspiratory – Corrugated 10mm<br>Expiratory – Corrugated 10mm | Inspiratory – Corrugated 10mm<br>Expiratory – Corrugated 10mm | Similar |
| **Therapeutic use** | Non-invasive<br>Invasive | Non-invasive<br>Invasive | Similar |
| **Flow rates** | RT265 | Non-invasive – 5-30 lpm | Similar |

| | Predicate<br>Fisher & Paykel<br>RT265 Dual Heated Infant Breathing Circuit | Subject device<br>Vincent Medical<br>inspired™ 510-009 Infant Heated Breathing Circuit | Comparison |
|---|---|---|---|
| | Not distinguished between invasive and non-invasive<br>> 4 L/min | Invasive – 5-30 lpm | |
| **Maximum operating pressure** | 8 kPa (80cm$H_2O$) | 80 cm$H_2O$ | Similar |
| **Compatibility with the environment and other devices** | Compatible with F&P MR850 humidifier and F&P MR290 humidification chamber | To be used with VHC10 (infant) / VHC20 (adult) Auto-feed Humidification Chamber. Compatible with inspired™ VHB20 Heated Humidifier. | Similar<br>VHB20 (K222351) has been cleared under 510(k) and is equivalent to MR850. VHB20 has demonstrated compatibility with RT265 in K222351. |
| **Performance Standards (Standards met)** | ISO 5367<br>ISO 5356<br>ISO 8185<br>IEC 60601-1<br>IEC 60601-1-2 | ISO 5367<br>ISO 5356-1<br>ISO 80601-2-74<br>IEC 60601-1<br>IEC 60601-1-2 | Similar<br>ISO 8185 has been replaced by ISO 80601-2-74. |
| **Electrical Safety and EMC** | IEC 60601-1<br>IEC 60601-1-2 | IEC 60601-1<br>IEC 60601-1-2 | Identical |
| **Active Controller** | No, humidifier controlled | No, humidifier controlled | Identical |
| **Power / Energy Source** | Wire resistance provides heat to the air passing through the tubing to reduce the water condensation in the breathing system. | Wire resistance provides heat to the air passing through the tubing to reduce the water condensation in the breathing system. | Similar<br>ISO 8185 has been replaced by ISO 80601-2-74. |
| **Biocompatibility** | ISO 10993-1 | ISO 10993-1<br>ISO 18562-1 | Similar |

## Table 3 - Humidification Chamber Comparison of Subject vs. Predicate

| | Subject device<br>Vincent Medical<br>inspired™ Auto-feed Humidification Chamber<br>VHC10 and VHC20 | Predicate<br>Fisher & Paykel<br>MR290 Humidification Chamber | Comparison |
|---|---|---|---|
| **K#** | K252066 | K934140 | |
| **Product Code** | BTT | BTT | Similar |
| **CFR** | 21 CFR 868.5450 | 21 CFR 868.5450 | Similar |
| **Patient Population** | Adult and infant | Any patient using a heated humidifier | Similar |
| **Intended use environment** | Hospital | Hospital | Similar |
| **Sterility** | Non-sterile | Non-sterile | Similar |
| **Indications for Use** | This inspired™ Auto-feed Humidification Chamber acts as a reservoir for water for inhalation. In conjunction with a humidifier, this water is heated to warm and humidify medical gases delivered to adult and infant patients experiencing respiratory conditions requiring mechanical ventilation, positive pressure breathing assistance or other respiratory support. This is a non-sterile single use product. To be used by trained clinical personnel in a hospital environment only. Compatible with the inspired™ VHB20 Heated Humidifier. | The MR290 Humidification Chamber is intended to hold water required to humidify the air being delivered to patients. The MR290 is an auto-fill humidification chamber suitable for all patients and compatible with all F&P MR-series humidifiers. | Similar |
| **Principle of Operation** | The humidification chamber works with a respiratory humidifier (also called a “heater base”) that provides the heat source, temperature control systems, and alarm systems to heat and humidifies respiratory gases. | The humidification chamber works with a respiratory humidifier (also called a “heater base”) that provides the heat source, temperature control systems, and alarm systems to heat and humidifies respiratory gases. | Similar |
| **Compatibility with the environment and other devices.** | Compatible with inspired™ VHB20 Heated Humidifier | Compatible with F&P MR850 Respiratory Gas Humidifier. | Similar<br>VHB20 (K222351) has been cleared under 510(k) and is equivalent to MR850.<br>VHB20 has demonstrated compatibility with MR290 in K222351. |
| **Active Controller** | No – Humidifier controlled | No – Humidifier controlled | Similar |
| **Connection** | 22 mm ISO conical connections for breathing circuit | 22 mm ISO conical connections for breathing circuit | Similar |

| | Subject device<br>Vincent Medical<br>inspired™ Auto-feed Humidification Chamber<br>VHC10 and VHC20 | Predicate<br>Fisher & Paykel<br>MR290 Humidification Chamber | Comparison |
|---|---|---|---|
| | attachment<br>Flexible tubing bonded to close piercing device (spike) and chamber inlet for supplying water | attachment<br>Flexible tubing bonded to close piercing device (spike) and chamber inlet for supplying water | |
| **Design** | Maximum water line mark for visual confirmation of proper water levels | Maximum water line mark for visual confirmation of proper water levels | Similar |
| | Clear Housing to allow visibility of water level for monitoring | Clear Housing to allow visibility of water level for monitoring | Similar |
| **Maximum operating pressure** | 8 kPa (80 cmH2O) | 8 kPa (≈80 $cmH_2O$) | Similar |
| **Volume (ml)** | VHC10: Maximum water capacity – 180<br>Compressible volume (empty) – 300<br>Compressible volume (max water level) – 120<br>VHC20: Maximum water capacity – 180<br>Compressible volume (empty) – 440<br>Compressible volume (max water level) – 260 | MR290: Maximum water capacity – 158<br>Compressible volume (empty) – 350<br>Compressible volume (max water level) – 192 | Similar |
| **Humidity Output** | Invasive mode: ≥33 mg/l<br>Non Invasive mode: ≥12 mg/l | Invasive mode: 39.2 mg/L<br>Non Invasive mode: 24.6 mg/L<br>From K160764 | Similar<br>All comply with ISO 80601-2-74. |
| **Continuous Gas Flow Rate** | VHC10:<br>Invasive – 5-30 lpm<br>Non-invasive – 5-30 lpm<br><br>VHC20:<br>Invasive – 5-60 lpm<br>Non-invasive – 5-120 lpm | Invasive – 0-60 lpm<br>Non-invasive – 0-120 lpm | Similar |
| **Compliance** | VHC10: ≤ 1.5 ml/$cmH_2O$ @(60±3)$cmH_2O$<br>VHC20: ≤ 4 ml/$cmH_2O$ @(60±3)$cmH_2O$. | 0.4 ml/$cmH_2O$<br><br>5.54 mL/kPa(≈0.554ml/$cmH_2O$) From K160764 | Similar |
| **Resistance to Flow** | VHC10: ≤0.74$cmH_2O$/L/min @2.5L/min<br>VHC20: ≤0.06$cmH_2O$/L/min @30L/min. | 0.52 cmH2O @60L/min | Similar |
| **Gas leakage** | ≤10 ml/min @60 $cmH_2O$. | <10 mL/min @60 $cmH_2O$. | Similar |
| **Enthalpy Maximum Value**<br>**Enthalpy Averaged Value** | VHC10: 194.29 kJ/m³ Max.<br>VHC20: 194.47 kJ/m³ Max. | 151 kJ/kg Max.<br>120 kJ/kg Avg. | Similar<br>All comply with ISO |

| | Subject device<br>Vincent Medical<br>inspired™ Auto-feed Humidification Chamber<br>VHC10 and VHC20 | Predicate<br>Fisher & Paykel<br>MR290 Humidification Chamber | Comparison |
|---|---|---|---|
| | | Data from K160764 | 80601-2-74. |
| **Duration for Use** | 14 days | 14 days | Similar |
| **Shelf life** | 1 year (24 months) | No Provided. | Similar |
| **Material** | Uses Polypropylene for float frame | Uses Polycarbonate for float frame | Similar |
| **Performance standards (Standards Met)** | ISO 5367<br>ISO 5356-1<br>ISO 80601-2-74<br>IEC 60601-1 | ISO 5367<br>ISO 5356<br>ISO 8185<br>IEC 60601-1 | Similar<br>ISO 8185 has been replaced by ISO 80601-2-74. |
| **Electrical Safety and EMC** | IEC 60601-1 | IEC 60601-1 | Similar |
| **Power / Energy Source** | Electrical energy within heater base is used to raise the temperature and humidity if the gas delivered to the patient. | Electrical energy within heater base is used to raise the temperature and humidity if the gas delivered to the patient. | Similar |
| **Biocompatibility** | ISO 10993<br>ISO 18562 | Tested to applicable<br>ISO 10993 | Similar |

**Difference Between Subject and Predicate**

There are some differences between the subject device and predicate. These differences include some performance to applicable clauses of ISO 80601-2-74 but the differences between the predicate and subject device are all within the acceptance criteria of the standard. These differences do not raise safety concerns of substantial equivalence compared to the predicate.

**Substantial Equivalence Discussion**

**Tables 1, 2, and 3** above compares the key features of the subject device with the identified predicate – Fisher & Paykel RT380 and RT 385 Adult Evaqua 2 Dual Heated Breathing Circuit, K122432, Fisher & Paykel RT265 Dual Heated Infant Breathing Circuit, K103767, Fisher & Paykel MR290 Humidification Chamber, K934140. The comparison demonstrates that the subject devices can be found to be substantially equivalent.

**Indications for Use –**
The indications for use are similar for the subject device when compared to the predicate device.
**Discussion –** The subject and predicate device have equivalent flow, humidification and heating ranges.

**Technology and construction –**
The technology to heat and humidify gases is similar that both devices use identical heater wire for Heated Breathing Circuit and identical base for Humidification Chamber.
**Discussion –** There are no differences that raise concerns of substantial equivalence.

**Environment of Use –**
The environments of use are similar to predicate which are clinical settings.
**Discussion –** The environments of use are the same.

**Patient Population –**
The patient population of the subject device is infant to adult, which is more restrictive than the predicate which is neonate to adult.
**Discussion –** The subject device's patient population is within the population limits of the predicate.

**Non-Clinical Testing Summary –**

**Bench testing –**
We performed tests related to demonstrate:

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ISO 80601-2-74 First edition 2017-05 - Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- ISO 5356-1 Third edition 2004-05-15 - Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
- ISO 5367 Fifth edition 2014-10-15 - Anaesthetic and respiratory equipment - Breathing sets and connectors
- ASTM F1980-16 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169-22 - Standard Practice for Performance Testing of Shipping Containers and Systems

**Discussion –** Nonclinical testing was performed comparing the predicates to the subject devices following the above listed standards. This testing included electrical safety and EMC and the performance of temperature and humidification output at various flow rate and temperature settings. In addition, testing for leakage, compliance, resistance to flow, transportation and storage and effects of storage and aging were evaluated.

**Biocompatibility –**
The patient contact and duration of use is externally communicating, tissue with permanent duration of use (> 30 days). We performed the applicable ISO 10993 and ISO 18562.

- ISO 10993-5 Third edition 2009-06-01 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10 Fourth edition 2021-11 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11 Third edition 2017-09 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-23 First edition 2021-01 - Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 10993-18 Second edition 2020-01 Amendment 1 2022-05 - Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 18562-2 First edition 2017-03 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3 First edition 2017-03 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds

**Discussion –** The subject materials were found to meet the applicable requirements for biocompatibility safety for the intended population.

## Substantial Equivalence Conclusion

Non-clinical testing, including performance testing, and design and features comparisons have demonstrated that the subject devices are substantially equivalent to the predicate devices.